

PATENT COOPERATION TREATY

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INTERNATIONAL SEARCH REPORT

Bromberg & Sunstein, LLP

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 2960/132WO	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, Item 5 below.	
International application No. PCT/US2006/045172	International filing date (day/month/year) 22/11/2006	(Earliest) Priority Date (day/month/year) 23/11/2005
Applicant CONFORMIS, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 5 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of:

☒ the international application in the language in which it was filed
☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

- b. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☒ Certain claims were found unsearchable (See Box No. II)3. ☐ Unity of invention is lacking (see Box No. III)4. With regard to the **title**,

☒ the text is approved as submitted by the applicant
☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant
☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. 2

☒ as suggested by the applicant
☐ as selected by this Authority, because the applicant failed to suggest a figure
☐ as selected by this Authority, because this figure better characterizes the invention

- b. ☐ none of the figures is to be published with the abstract

A. CLASSIFICATION OF SUBJECT MATTER
 INV. A61B17/88 A61F2/46

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
 EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 591 165 A (JACKSON ROGER P [US]) 7 January 1997 (1997-01-07)	1-10, 21-28, 53-55
A	abstract; figures 15a,15b -----	11,56
X	WO 03/028566 A (STRYKER SPINE [FR]; SAINT MARTIN PIERRE HENRI [FR]; VIENNEY CECILE [FR] 10 April 2003 (2003-04-10)	1-10,21, 26-28, 53-55
A	abstract; figures 3-6 -----	11,56
X	US 2005/119751 A1 (LAWSON KEVIN J [US]) 2 June 2005 (2005-06-02)	1-10, 21-28, 53-55
A	----- -/-	11,56

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *S* document member of the same patent family

Date of the actual completion of the international search

11 April 2007

Date of mailing of the international search report

19/04/2007

Name and mailing address of the ISA/

European Patent Office, P.B. 5018 Patentlaan 2
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Authorized officer

Macaire, Stéphane

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 2 795 945 A1 (SCIENT X [FR]) 12 January 2001 (2001-01-12) abstract; figures 4-7 -----	1-28, 53-58
P, X	US 2006/074432 A1 (STAD SHAWN D [US] ET AL) 6 April 2006 (2006-04-06) abstract; figures 1-3 -----	1, 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2006/045172**Box II Observations where certain claims were found unsearchable (Continuation of Item 2 of first sheet)**

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 29-52
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of Item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5591165	A	07-01-1997	NONE	
WO 03028566	A	10-04-2003	EP 1458298 A1 FR 2830433 A1 US 2004249378 A1	22-09-2004 11-04-2003 09-12-2004
US 2005119751	A1	02-06-2005	NONE	
FR 2795945	A1	12-01-2001	AU 6295700 A EP 1194087 A1 WO 0103615 A1 US 6964687 B1 US 2005125029 A1	30-01-2001 10-04-2002 18-01-2001 15-11-2005 09-06-2005
US 2006074432	A1	06-04-2006	NONE	

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2006/045172

International filing date (day/month/year)
22.11.2006

Priority date (day/month/year)
23.11.2005

International Patent Classification (IPC) or both national classification and IPC
INV. A61B1788 A61F246

Applicant
CONFORMIS, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1 (a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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NL-2280 HV Rijswijk - Pays Bas
Tel.: +31 70 340 - 2040 Tx: 31 651 epo nl
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Date of completion of
this opinion

See form
PCT/ISA/210

Authorized Officer

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2006/045172

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in electronic form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2006/045172

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. 29-52

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international search (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

☒ no international search report has been established for the whole application or for said claims Nos. 29-52

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2006/045172

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>5,13,15,16,24-25</u>
	No: Claims	<u>1-4,6-12,14,17-23,26-28,53-58</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-28,53-58</u>
Industrial applicability (IA)	Yes: Claims	<u>1-28,53-58</u>
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item III.

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

Claims 29-52 refer to methods of grasping an implant. This action is only disclosed in combination with the insertion of the implant into the human body and forms part of a method for treatment of the human or animal body by surgery.

Therefore no search has been performed for claims 29-52 (Article 34(4)(a) PCT).

Re Item V.

- 1 Reference is made to the following documents:

D1 : US 5 591 165 A (JACKSON ROGER P [US]) 7 January 1997 (1997-01-07)

D2 : FR 2 795 945 A1 (SCIENT X [FR]) 12 January 2001 (2001-01-12)

- 2 INDEPENDENT CLAIMS 1, 11, 21, 53 and 56

- 2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

Document D1 discloses (the references in parentheses applying to this document):

A device for grasping an implant (figs. 15a, 15b), the implant for use in a joint and having a first and second surface (fig. 16), at least one of the first and second surfaces being non-planar, the grasper device comprising:

a first grasping element (72) including a first grasping surface substantially conforming to the first surface of the implant;

a second grasping element (69) including a second grasping surface substantially conforming to the second surface of the implant;

wherein at least one of the first grasping element and the second grasping element can be moved to grasp the implant, such that the first grasping surface contacts the first surface of the implant and the second grasping surface contacts the second surface of the implant (col. 15, l. 14-25).

- 2.2 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 11 is not new in the sense of Article 33(2) PCT.

Document D2 discloses (the references in parentheses applying to this

document):

A surgical instrument (fig. 4) for grasping an implant having a first and second surface, the implant for use in a joint (intervertebral joint), at least one of the first and second surfaces (2, 20) being non-planar (fig. 1), the surgical instrument comprising:

- a first grasping element (16, 21);

- a second grasping element (16, 21);

- wherein at least one of the first grasping element and the second grasping element can be moved to grasp the implant such that the first grasping element contacts the first surface of the implant and the second grasping element contacts the second surface of the implant, and wherein at least one of the first grasping element and the second grasping element is made of a pliable material (p. 7, l. 9-14).

- 2.3 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 21 is not new in the sense of Article 33(2) PCT.

Document D1 discloses:

An implant system comprising:

- an implant (fig. 15) having first and second surfaces facing in substantially opposite directions, the first surface including a first indentation; and

- an implant grasper (figs. 15a, 15b) for gripping the implant, the implant grasper including a first grasping element and a second grasping element;

- wherein the first indentation (73) has peripheral walls that prevent rotation of the implant when the first grasping element (77) is received by the first indentation and the second grasping element of the implant grasper contacts the second surface to grasp the implant.

- 2.4 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 53 is not new in the sense of Article 33(2) PCT.

Document D1 discloses a set comprising the grasping device according to claim 1 and the implant (fig. 16).

- 2.5 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 56 is not new in the sense of Article 33(2) PCT.

Document D2 discloses a set comprising the surgical instrument according to claim 11 and the implant (fig. 1).

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/US2006/045172

7 DEPENDENT CLAIMS 2-10, 12-20, 22-28, 54, 55, 57, 58

Dependent claims 2-10, 12-20, 22-28, 54, 55, 57, 58 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT).